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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,759

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Gary Mark Coppola

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02/17/2010

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.
220 MASSACHUSETTS AVENUE
CAMBRIDGE, MA 02139

EXAMINER

MABRY, JOHN

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

02/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,759	Applicant(s) COPPOLA ET AL.	
	Examiner JOHN MABRY	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9, 12, 13, 25-33 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 18-20 and 22 is/are allowed.
- 6) ☒ Claim(s) 7-9, 12, 13, 18-20, 22, 33 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment(s)

Applicant's response on November 12, 2009 filed in response to the Office Action dated May 22, 2009 has been received and duly noted.

In view of this response, the status of the rejections/objections of record is as follows:

Status of the Claims

Claims 7-9, 12-13, 33 and 40 are pending and rejected.

Claims 18-20 and 22 is allowable.

Claims 1-6, 10-11, 14-17, 21, 23-24 and 34-39 have been cancelled.

Claims 25-32 directed towards non-elected subject matter.

Claim 40 is new.

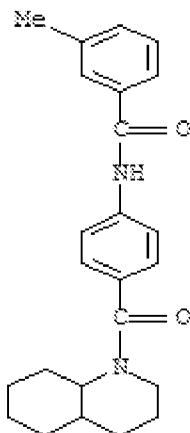
35 USC § 112 Rejection(s)

The 112-1st rejection of claims 7-9, 12-13, 18-20, 22 and 33 regarding the scope of enablement have been overcome in view of Applicant amending the claims.

Claim Rejections - 35 USC § 102

Rejections of claims 7, 8, 33 and 40 are maintained under 35 U.S.C. 102(b) as being anticipated by Ogawa et al (WO 9401113 A1).

Ogawa et al clearly discloses compounds and pharmaceutical compositions of Formulas Ia wherein R13 and R14=H, X and Y=CH, R1 and R2=H and W=NR5C(O)R6 wherein R5=H and R6=methylphenyl (see compound 2-149, page 146).



Applicant argues that this rejection should be withdrawn due to Applicant's amendments to the claims i.e. the phenyl group of R6 not being substituted by alkyl. Examiner respectfully disagrees with Applicant's allegation. Variable R6 of the most recently set of amended claims reads as follows:

~~R₆ is optionally substituted C₁₋₄ alkyl, phenyl, naphthyl, thienyl, furanyl, pyrrolyl, morpholinyl, piperidinyl, piperazinyl, pyridinyl, benzothienophenyl, benzodioxoxyl or aryl, heteroaryl, cycloalkyl, aralkyl or heteroaralkyl, wherein said aryl is each of which may be optionally substituted by one to four substituents such as halo, hydroxy, alkoxy, alkanoyl, alkanoyloxy, optionally substituted amino, thiol, alkylthio, nitro, cyano, carboxy, carboxyalkyl, alkoxy-carbonyl, alkylthiono, alkyl- and arylsulfonyl, sulfonamido and heterocycloyl;~~

Examiner would like to point to the claim language - "may be optionally substituted" and "such as". The phrase "may be optionally substituted" is inclusive or open-ended language which Examiner interprets to mean that the phenyl group of R6 may or may not be substituted. Under this interpretation, the instant claimed invention remains anticipated by Ogawa.

The phrase "such as" is inclusive or open-ended language which Examiner interprets to mean "for example" where such substituents on the phenyl group of R6

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may or may not be substituted by substituents listed. Under this interpretation, the instant claimed invention remains anticipated by Ogawa.

NOTE: Additionally, due to Applicant's amendments to the claims, a new ground of obviousness rejection is made below in view of Ogawa et al (WO 9401113 A1) under "DETAILED ACTION".

Claim Rejections - 35 USC § 103

Rejections of claims 7, 8, 9, 33 and 40 are maintained under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al (WO 9401113 A1). Examiner made the case that the instant claimed invention would be deemed obvious in view the compounds and teachings of Ogawa et al (see original rejection in previous Non-Final Office Action dated 5/22/09).

Applicant argues that the instant invention is inhibitors of 11 β -hydroxysteroid dehydrogenase type 1 reductase activity and Ogawa's disclosure are oxytocin inhibitors. Applicant attempts to differentiate the instant invention and disclosure of Ogawa by pointing out this difference. Essentially, Applicant is claiming to treat diseases and disorders such as diabetes and central obesity. It is established in the prior art that inhibition of oxytocin is used to treat central obesity, weigh loss and diabetes (see Bray et al Handbook of Obesity-Etiology and Pathophysiology, Second Edition, 2003 and Olson et al Peptides 1991, page 113, abstract). Therefore, the

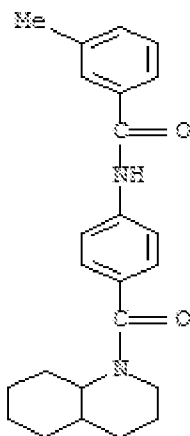
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compounds of the instant invention and the compounds of Ogawa are used to treat similar diseases and disorders as claimed.

Applicant argues that Ogawa et al fails to teach or suggest specific compounds in the genus of claim 7 and further fails to teach or suggest specific compounds of claims 8 and 9. Examiner respectfully disagrees with Applicant's allegations. Examiner clearly set forth the reasoning for the instant application being deemed obvious over Ogawa et al (WO 9401113 A1). For purposes of convenience, the rejection is repeated below:

Scope & Content of Prior Art MPEP 2141.01

Ogawa et al discloses compounds and pharmaceutical compositions of Formula Ia wherein R13 and R14=H, X and Y=CH, R1 and R2=H and W=NR5C(O)R6 wherein R5=H and R6=methylphenyl (see compound 2-149, page 146).



Differences between Prior Art & the Claims MPEP 2141.02

Ogawa and the instant application differs at the R1 position: Ogawa's H versus Applicant's CH₃. A hydrogen (H) and methyl (-CH₃) are deemed obvious variants (*In re Wood*, 199 USPQ 137).

Furthermore, the genus of Formula 2, page 11 of the reference by Ogawa teaches R₁₇ = H, halogen, lower alkoxy, and lower alkyl and substituted amino (see page 11, definition of R₁₇). These teachings of Ogawa are the same that are being claimed by Applicant. Thus said, claims are rendered obvious Ogawa.

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

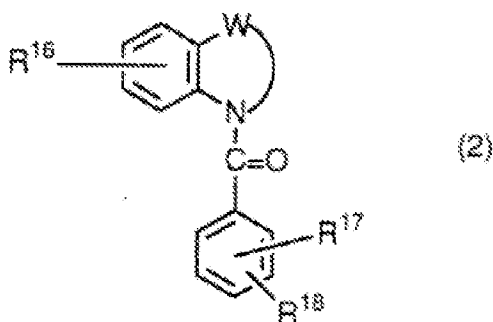
It would be "obvious" for one of ordinary skill "to try" to make compounds of Formula 1a choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success from the disclosed compounds and teachings of Ogawa. In further view of Ogawa's species, teachings and suggestions would lead one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

In order to further refute Applicant's allegation that a genus of claim 7 was not taught or suggested by Ogawa et al, the following has been provided to further support Examiner's argument.

As pointed out in previous obviousness rejection (and as shown above), Ogawa et al illustrates the following genus (see page 11 of Ogawa et al). The reference by Ogawa teaches R₁₇ = H, halogen, lower alkoxy, and lower alkyl and substituted amino

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(see page 11, definition of R17). These teachings of Ogawa are the same as being claimed by Applicant. Thus said, claims are rendered obvious Ogawa. The genus is directly related to the claimed genus of Ia.



The genus above shows bicyclic heterocyclic ring which can be tetrahydroquinolyl as shown in species 2-149 (page 146) – see above rejection. Ogawa et al teach or suggest specific compounds of claims 8 and 9 (see reasoning above and below in 102 and 103 arguments).

The heterocyclic ring in the formula (2) includes tetrahydroquinolyl, 2,3,4,5-tetrahydro-1H-benzazepinyl, 1,2,3,4,5,6-hexahydrobenzazocinyl, 1,2-dihydroquinolyl, 2,3-dihydro-1H-benzazepinyl, 1,2,3,4-tetrahydrobenzazocinyl, and the like.

(see page 96 of Ogawa, third full paragraph from the top).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

An action on the merits of claims 7, 8, 9, 33 and 40 is contained herein below.

DETAILED ACTION

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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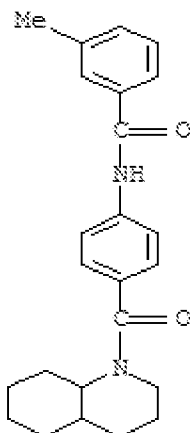
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 8, 9, 33 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al (WO 9401113 A1).

Applicant claims compounds and pharmaceutical compositions of Formula Ia wherein R13 and R14=H, X and Y=CH, R1 and R2=H and W=NR5C(O)R6 wherein R5=H and R6=phenyl.

Scope & Content of Prior Art MPEP 2141.01


Ogawa et al discloses compounds and pharmaceutical compositions of Formula Ia wherein R13 and R14=H, X and Y=CH, R1 and R2=H and W=NR5C(O)R6 wherein R5=H and R6=methylphenyl (see compound 2-149, page 146).



Differences between Prior Art & the Claims MPEP 2141.02

Ogawa and the instant application differs at the substitution of the R6 position: Ogawa's CH₃ versus Applicant's "optionally substituted phenyl". For purposes of comparison, Applicant's phenyl will be unsubstituted in which means a hydrogen (H).

Ogawa discloses R17 (Applicant's R5) equals H; R18 equals -NR¹⁹R²⁰ where

R²⁰ equals  where r=0 (Applicant's W=-NR⁵C(O)R⁶ where R⁵=H and R⁶ equals phenyl which is optionally substituted (see page 11, Formula 2, variables R¹⁷-R²⁰ and page 12, lines 16-17). For purposes of comparison, Applicant's phenyl will be unsubstituted in which means a hydrogen (H).

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

It would be "obvious" for one of ordinary skill "to try" to make compounds of Formula Ia choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success from the disclosed compounds and teachings of Ogawa. In further view of Ogawa's species, teachings and suggestions would lead one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. These teachings of Ogawa are the exact same that are being claimed by Applicant. Thus said, claims are rendered obvious Ogawa.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/
Examiner
Art Unit 1625

/Rita J. Desai/

Primary Examiner, Art Unit 1625